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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,044	03/29/2004	Colin H. Self	602314-004	1445

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EXAMINER	
LUNDGREN, JEFFREY S	
ART UNIT	PAPER NUMBER
1639	
MAIL DATE	DELIVERY MODE
09/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,044	SELF ET AL.	
	Examiner	Art Unit	
	JEFFREY S. LUNDGREN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/2/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,15,16 and 18-23* is/are pending in the application.

4a) Of the above claim(s) *15,16 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1, 15, 16 and 18-23 are pending in the instant application; claims 15, 16 and 18 are withdrawn from consideration; claims 1 and 19-23 are the subject of the Office Action below.

Applicants' Petition to Accept Unintentionally Delayed Priority – Denied

It is noted that Applicants' Petition to Accept Unintentionally Delayed Priority Claim Under 37 C.F.R. § 1.78(a)(3) and 1.55(c), has been dismissed by the Office of Petitions, and communicated in the Decision mailed on August 19, 2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Maintained Rejections:

The rejection of claims 1 and 22, under 35 U.S.C. 102(b) as being anticipated by each of: Eby R., *Carbohydrate Research 70(1)*:75-82 (**1979**); Thompson *et al.*, *Biochemical and Biophysical Research Communications 201(3)*:1213-1219 (**1994**), Goldmacher *et al.*, *Bioconjugate Chemistry 3(2)*:104-7 (**1992**), and Rothschild *et al.*, U.S. Patent No. 6,589,736, issued on July 8, 2003, are all maintained in view of Applicants' petition for priority being denied.

Applicants contend that the rejections are moot in view of their amendment to the specification claiming priority to PCT/GB94/02359 and British Application No. 9322156.2,

thereby removing the cited art as prior art. Applicants also content that their amended claims no longer read on the prior art. Both arguments have been fully considered, however neither is persuasive.

First, Applicants' are not entitled to priority of applications PCT/GB94/02359 and British Application No. 9322156.2 for the reasons set forth above.

Second, Applicants claims still read on the art of record for the reasons provided in the following rejections below.

The rejection of claims 1 and 19-23, under 35 U.S.C. 102(b) as being anticipated by each of: Thompson *et al.*, *Biochemical and Biophysical Research Communications 201(3)*:1213-1219 (**1994**), and Goldmacher *et al.*, *Bioconjugate Chemistry 3(2)*:104-7 (**1992**), are all maintained.

Claim 1 is directed to a composition, wherein the composition comprises a core molecule having one or more active sites, and a plurality of smaller labile residues reversibly attached to the core molecule. The attachment of the labile residues causes an alteration in the core's binding, and the labile residue is dissociable under electromagnetic energy, such that the active site regains activity.

Claim 19 is similar to claim 1, but specifies the core as an antibody. Claims 20 and 21 specify that the labile residue is 2-nitrobenzyloxycarbonyl. Claims 22 and 23 limit the electromagnetic radiation to UV light.

Claims 1 and 22 are anticipated by Eby:

Eby teaches an oligosaccharide (*i.e.*, core molecule) modified with 2-(4-nitrophenyl)ethanol (*i.e.*, smaller labile residues) on multiple active sites (pages 76 and 77), and teaches that the activity of modified active sites effects activity, *i.e.*, the nonterminal residues along the dextran chain (page 78), and the residues have the property of being labile under electromagnetic energy and that reversibly restore the oligosaccharide activity with its antibody, and the composite is sensitive to UV light, as required by claims 22.

Claims 1 and 19-23, are anticipated by Thompson:

Thompson teaches methods to allow the reversible binding of up to 15 nitrobenzyl residues per bovine serum albumin mol. and show 95% of these residues can be removed by exposure to UV light for 10 minutes. Thompson not only teaches that the general non-specific coating method can be presented by a model system, but is applicable to a wide range of proteins with important biological functions. Potentially, any protein could be coated with sufficient photo-removable groups to inhibit its biological function. Thompson teaches that the activity may then be restored at will by exposure to UV light removing the coupled 2-nitrobenzyl groups.

Claims 1 and 19-23 are anticipated by Goldmacher:

Goldmacher teaches a novel photocleavable protein cross-linking reagent that has been used for conjugation of the ribosome-inactivating protein pokeweed antiviral protein from seeds of *Phytolacca americana* (PAP-S), with either the monoclonal antibody 5E9 directed against the human transferrin-receptor or the B-chain of ricin that binds to cell-surface oligosaccharides bearing terminal D-galactose residues. When irradiated with near-UV light (350 nm), the linker of these conjugates undergoes photolytic degradation, resulting in the release of native toxin that is fully functional. The cytotoxicities of these 5E9-PAP-S and ricin B-chain-PAP-S conjugates for HeLa cells could be enhanced by irradiating the cells with light after they had internalized the conjugates. The labile residue is the HN-RIP that is attached via the 2-(4-nitrophenyl)ethanol, which in turn is attached to the antibody. Although the "labile" 2-(4-nitrophenyl)ethanol is not directly bound to the antibody, each of the claims read on Goldmacher.

Accordingly, claims 1 and 19, 20, 22 and 23, are anticipated by the art of record.

Claims 1 and 19-23, are anticipated by Rothschild:

Claims 1 and 19-23, are rejected under 35 U.S.C § 102(e), as being anticipated by Rothschild *et al.*, U.S. Patent No. 6,589,736, issued on July 8, 2003.

Claim 1 is directed to a composition, wherein the composition comprises a core molecule having one or more active sites, and a plurality of smaller labile residues reversibly attached to the core molecule. The attachment of the labile residues causes an alteration in the core's binding, and the labile residue is dissociable under electromagnetic energy, such that the active site regains activity.

Claim 19 is similar to claim 1, but specifies the core as an antibody. Claims 20 and 21 specify that the labile residue is 2-nitrobenzyloxycarbonyl. Claims 22 and 23 limit the electromagnetic radiation to UV light.

Rothschild teaches agents and conjugates that can be used to detect and isolate target components from complex mixtures such as nucleic acids from biological samples, cells from bodily fluids, and nascent proteins from translation reactions. Agents comprise a detectable moiety bound to a photoreactive moiety. Conjugates comprise agents coupled to substrates by covalent bounds which can be selectively cleaved with the administration of electromagnetic radiation. Targets substances labeled with detectable molecules can be easily identified and separated from a heterologous mixture of substances. Exposure of the conjugate to radiation releases the target in a functional form and completely unaltered. Using photocleavable molecular precursors as the conjugates, label can be incorporated into macromolecules, the nascent macromolecules isolated and the label completely removed (see Summary of the Invention). Rothschild teaches an antibody attached via a 2-nitrobenzyloxycarbonyl group (see Figs. 4, 7 and 12, and description thereof).

Accordingly, the claims are anticipated.

Conclusions

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If Applicants should amendment the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James (Doug) Schultz, can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSL

/JD Schultz, PhD/

Supervisory Patent Examiner, Art Unit 1635